Form: TH-04



# Emergency Regulation Agency Background Document

Agency Name:	Agency Name: Board of Dentistry, Department of Health Professions	
VAC Chapter Number:	18 VAC 60-20-10 et seq.	
Regulation Title:	Regulations Governing the Practice of Dentistry and Dental Hygiene	
Action Title:	Registration/certification of oral & maxillofacial surgeons	
Date:	7/25/01	

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

# **Emergency Preamble**

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

Emergency regulations are required for compliance with an enactment clause in Chapter 662 of the 2001 Acts of the Assembly requiring the Board to promulgate regulations within 280 days of enactment to implement provisions of the act requiring the Board of Dentistry to establish requirements for the registration and profiling of oral and maxillofacial surgeons and for the certification of such persons to perform certain cosmetic procedures.

#### **Basis**

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Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The legal authority to promulgate the emergency regulation is in third enactment clause of Chapter 662 of the 2001 Acts of the Assembly, which states: "That the Board of Dentistry shall promulgate regulations to implement the provisions of subdivision 12 of subsection A of § 54.1-2706, §§ 54.1-2709.1 and 54.1-2709.2 within 280 days of the enactment of this act." See complete copy of SB 806 (Chapter 662) - <a href="http://leg1.state.va.us/cgi-bin/legp504.exe?011+ful+CHAP0662">http://leg1.state.va.us/cgi-bin/legp504.exe?011+ful+CHAP0662</a>

The Office of the Attorney General has certified that the "emergency situation" which exists is specified in § 9-6.14:4.1 (C)(5)(ii) of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law.

#### **Substance**

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

In mandating certification of oral and maxillofacial surgeons to perform cosmetic procedures on the head and neck, § 54.1-2709.1 requires that regulations include six specific criteria – the first of which is the "promotion of patient safety." Regulations establishing a profile of such surgeons (including disciplinary and malpractice history), standards for minimal competency in performing certain procedures, and a system for quality assurance review of their practice are all intended to protect the health, safety and welfare of citizens of Virginia who may elect to become cosmetic surgery patients. Similar requirements and oversight of practice by a regulatory board does not exist for any other health care professional, but were included to fulfill a statutory mandate in the interest of patient safety.

The specific provisions of emergency regulations are as follows:

### 18 VAC 60-20-10. Definitions.

A definition for "proctored cases" is added to clarify the term as used in requirements for certification of oral and maxillofacial surgeons.

# 18 VAC 60-20-250. Registration of oral and maxillofacial surgeons.

Pursuant to a statutory mandate in § 54.1-2709.2 of the Code, the Board is required to annually register all oral and maxillofacial surgeons and to report certain information to the public. Regulations implementing this mandate require an annual fee of \$175, which is intended to cover the cost of a public profile system for the surgeons. Fees for late renewal or reinstatement of a lapsed registration are also set.

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# 18 VAC 60-20-260. Profile of information for oral and maxillofacial surgeons.

This section lists the specific information the practitioner is required to submit and be included on a public profile. It also requires the submission to occur within 30 days of an initial request or of a change in the information.

# 18 VAC 60-20-270. Reporting of malpractice paid claims.

Specifics about the reporting of malpractice claims are set forth in this section, including the period of time that is covered, the content of the report, and the definitions of relative amounts of the claims.

# 18 VAC 60-20-280. Non-compliance or falsification of profile.

Failure to provide required information may constitute unprofessional conduct by the licensee; intentional falsification of information is unprofessional conduct and will subject the licensee to disciplinary action.

#### 18 VAC 60-20-290. Certification to perform cosmetic procedures; applicability.

Subsection A establishes the applicability for the need to be certified and the anatomical limitation for which surgeries may be performed under such certification.

Subsection B lists the specific procedures for which a surgeon may be certified depending on the qualifications and competencies he demonstrates.

# 18 VAC 60-20-300. Certification not required.

This section lists the specific procedures for which a surgeon need not be certified, but are considered within the current scope of practice for an oral and maxillofacial surgeon.

# 18 VAC 60-20-310. Credentials required for certification.

This section sets forth the credentials required for certification to perform cosmetic procedures. Those credentials include an active, unrestricted license from the board, a fee of \$225, an oral and maxillofacial residency from an accredited dental program, board certification or eligibility in oral and maxillofacial surgery, current privileges in a hospital and documentation of education and experience in performance of cosmetic procedures.

# 18 VAC 60-20-320. Renewal of certification.

Each oral and maxillofacial surgeon who wishes to renew his certification must pay a fee of \$100 by December 31<sup>st</sup> of each year.

# 18 VAC 60-20-330. Quality assurance review for procedures performed by certificate holders.

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Provisions are adopted for a quality assurance review as mandated in subdivision 6 of § 54.1-2709.1 A. Certifying bodies, such as the Joint Commission on Accreditation of Healthcare Organizations, conduct quality assurance reviews on procedures performed in facilities they accredit. Therefore, the Board will require a random audit of charts and quality assurance review for cosmetic procedures not performed in an accredited facility. Costs for the review will be covered by the certification and renewal fees paid by certified oral and maxillofacial surgeons. The Board will use persons qualified to perform cosmetic procedures as reviewers and will require surgeons to maintain a separate system by which charts on those patients may be identified.

# **Alternatives**

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

The Board has a statutory mandate to promulgate regulations establishing a registration of oral and maxillofacial surgeons and a certification of board certified or board eligible surgeons to perform certain procedures. Regulations for the registration of oral and maxillofacial surgeons for the purpose of producing a profile of those practitioners were based on a similar requirement for physicians. Regulations for certification to perform cosmetic surgery were more difficult since there are few models to consider. Therefore, the Board sought information from other states, credentialing bodies, schools of dentistry and medicine, and individual practitioners.

As mandated by the legislation, the Board was also required to consult with an advisory committee of persons named by the Medical Society of Virginia and by the Virginia Society of Oral and Maxillofacial Surgeons. That committee met on three occasions to review the mandate for certification and draft recommendations for certification, including the specific procedures that could be performed and the prerequisite qualifications. While the members were able to agree on several basic criteria for oral and maxillofacial surgeons, they remained in disagreement about the necessary education, the scope of certification, and the training and experience required for certification. Therefore, the report that was produced listed the areas of agreement and a side-by-side comparison of the differing recommendations from the two sides on what the requirements should be for oral and maxillofacial surgeons who want to perform cosmetic procedures.

Those areas of agreement included:

- Completion of an accredited oral and maxillofacial residency
- Board certification or board eligibility by the American Board of Oral and Maxillofacial Surgery
- Credentialing for surgical procedures involving certain anatomical areas within the head and neck region of the body
- Privileges as an oral and maxillofacial surgeon on a hospital staff

The areas of disagreement with the position of each profession represented were as follows:

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**Educational requirements** 

Medical	Dental
12 months of clinical rotations, including internal medicine and surgery	DDS or DMD degree with a residency in oral & maxillofacial surgery from a program accredited by the Commission on Dental Accreditation.

**Scope of Certification** 

Scope of Certification	
Medical  Certification can only be granted for the full	Dental  Credentialing by procedure. Every initial application for certification must contain a request
scope of procedures covered by this legislation and cannot support the certification of individual procedures	for the specific clinical certification desired by the applicant. The evaluation of the requests shall be based on the applicant's education, training, experience, demonstrated competence, and other
	relevant information.  Anatomical areas and surgical procedures which
	<ul> <li>will not need to be credentialed include:</li> <li>Treatment of facial diseases and injuries, including maxillofacial structures.</li> </ul>
	<ul><li>Facial Fractures</li><li>Cleft Lip and palate deformity</li><li>Facial deformity and wound treatment</li></ul>
	Mentoplasty and facial augmentation procedures
	Procedures requiring extra-oral incisions

# **Training and Experience**

Medical		Dental
A one-year clinical fellowship in esthetic surgery in accordance with the standards of the Commission on Dental Accreditation with a minimum of 125 proctored cases of esthetic surgery as follows:		Letter from the individual's program director documenting the training received in the residency-training program and/or fellowship training to substantiate adequate training in the specific areas of requested certification.
Procedure	Required Number of Cases (Total of 125)	<ul> <li>(minimum of 10 proctored cases in each area)</li> <li>2. Documentation of the various surgical procedures performed during residency training and/or fellowship training that specify</li> </ul>
Rhinoplasty Blepharoplasty	20 20	the number of procedures performed as a
Rhydidectomy	20	primary or assistant surgeon with appropriate supervision.
Genioplasty	10	Super vision.
Submental liposuction	10	
Laser resurfacing or	10	

dermabrasion	
Browlift (either open	15
or endoscopic	
technique)	
Platysmal muscle	10
plication	
Otoplasty	10

Requirements for current oral/maxillofacial surgeons

Requirements for oral/maxillofacial surgeons who did not meet the training/experience requirements during residency

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#### Medical

Educational courses that provide for 12 months of clinical rotations including internal medicine and surgery, or the equivalent thereof must be completed. Practicing surgeons must complete the same number of proctored cases required of resident surgeons. Surgical procedures that may have been performed in the past in an unsupervised or unproctored manner should not be considered to have the same educational value as proctored cases. Such cases would not count toward standard OMFS training and should not count towards training under the new definition of dentistry.

# Dental

- 1. Has completed both didactic and clinically approved courses in the specific area requested for certification.
- 2. Provide documentation of the number of hours of didactic and clinical training.
  - Dates attended
  - Location of training course
  - Copy of certificate of attendance (including the number of contact hours)
- 3. Documentation of any (if applicable) current privileges to perform cosmetic surgical procedures within a Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredited hospital
- 4. Documentation of the number of surgical procedures performed as a primary or assistant surgeon.

The report of the advisory committee with written recommendations was first submitted to the Board of Medicine for its comment. That board offered its opinions on issues related to the standards of education, the scope of certification, the surgical competence and patient safety, and the comparability of surgical training for maxillofacial and physician surgeons. In the opinion of the Board of Medicine, medical education, training and experience are necessary to ensure public safety for "non-physicians" who wish to perform cosmetic surgery.

Both the report of the advisory committee and the response of the Board of Medicine were reviewed and considered by the Board of Dentistry prior to its adoption of regulations. The alternatives recommended by both sides of the issue were presented, and the Board sought to promulgate regulations that addressed the specific components of the regulation required by subsection A of § 54.1-2709.1 as well as the concerns expressed about public safety. While the Board recognized that there are different pathways of education, training and experience for plastic surgeons and oral and maxillofacial surgeons, it contends that both have demonstrated their ability to practice with safety and competency. Prior to SB 806, oral and maxillofacial surgeons have been credentialed and have held hospital privileges to perform a variety of reconstructive surgeries in the area of the head and neck. There is no evidence that the public has been harmed by their practice, so the Board believes the regulations it has adopted are

sufficient to ensure that those procedures performed for cosmetic purposes may also be performed with competency and safety.

# Family Impact Statement

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Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The Board has determined that there is no impact on the family or family stability as a result of these regulations. Likewise, there should be no effect on disposable family income.